IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Christopher Batich et al.
Serial No. 09/965,740
Publication No. US 2002/0177828
Filed: 09/28/2001
For: Adsorbent Materials with Covalently Bonded, Nonleachable Polymeric Antimicrobial Surfaces, and Methods for Preparation
Atty. Docket No. QMT1.1-CIP-US
Group Art Unit: 3761
Examiner: Catherine Lynne Anderson

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132

Dr. James F. Kirk declares as follows:

Declarant

I am the Vice President of Research and Development at Nanotherapeutics in Gainesville, Florida. I make this statement in support of the patentability of U.S. patent application 09/965,740 (the "above-captioned application").

I have received academic degrees from the University of Florida and have assigned patents to the University of Florida Research Foundation. Nanotherapeutics has licensed several patents from the University of Florida Research Foundation, but otherwise I have no financial or consulting interest with either the University of Florida or the University of Florida Research Foundation. I have no financial investment in Quick-Med Technologies, Inc.

Quick-Med Technologies, Inc. and the University of Florida Research Foundation are both assignees of the above-captioned application.

Credentials

I received B.S. in Mechanical Engineering and M.S. degrees in Material Science and Engineering from the Massachusetts Institute of Technology and a Ph.D. degree in Material Science and Engineering from the University of Florida. I also obtained an MBA degree from Boston University.

I joined Nanotherapeutics in 2004 as Director of the Manufacturing Department to oversee the Nanotherapeutics' FDA-approved bone graft product Origen™ DBM with Bioactive Glass Bone Graft. Prior to joining Nanotherapeutics,

I held the position of Research manager at Regeneration Technologies, Inc. and Scientist positions at Vistakon and Genzyme.

I have co-authored or presented over 30 abstracts and have 6 patents, 5 of these in the fields of biomedical materials and polymers.

The attached CV further exemplifies my qualifications.

Introduction

My declaration is submitted to support the conclusion that the disclosure of U.S. 6,797,856 to Kolb et al. ("Kolb") does not disclose polymers of diallyldimethyl ammonium chloride ("polyDADMAC") as components, specifically binding agents, of a pant-like absorbent swimwear garment.

My attention was directed to column 6, lines 16-27 of Kolb which was cited by the Examiner in an office action. The Examiner had asserted that this passage within Kolb supported a disclosure of a composition comprising a substrate having a coating consisting of polymeric molecules formed by the polymerization of a diallyldialkylammonium salt, and more specifically, polymers of the monomer diallyldimethylammonium chloride (DADMAC), or poly(DADMAC). I was asked for my opinion on whether Kolb disclosed poly(DADMAC).

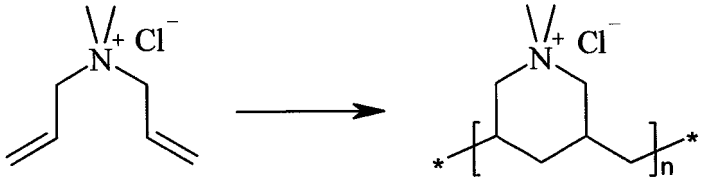
It is my opinion that Kolb does not disclose the use of poly(DADMAC), nor of polymers of a diallyldialkylammonium salt, as a binding agent component of a swimwear garment or swimpant.

Discussion

I have reviewed Kolb (U.S. Patent 6,797,856) as well as the specification and the pending claims of the above-captioned U.S. Patent Application 09/965,740.

The above-identified patent application exemplifies the use of polymers of diallyldimethylammonium chloride (DADMAC). When DADMAC is polymerized it forms poly(diallyldimethylammonium chloride) or polyDADMAC. Therefore, the above-identified patent application is concerned with polyDADMAC as a component of an antimicrobial substrate. The use of the monomer DADMAC as a component of the antimicrobial substrate is not taught by the inventors of the above-identified patent application.

The structural and chemical relationship of DADMAC to polyDADMAC is illustrated below.



DADMAC polyDADMAC

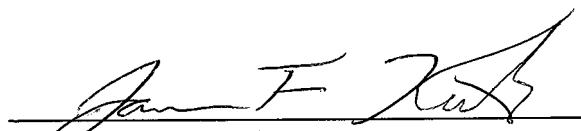
Within the passage of Kolb cited by the Examiner, suitable binding agents are described. Kolb lists many compounds as binding agents including cationic compounds, biological cationic polymers, inorganic cationic species, and polymer matrices [column 6, lines 16-19]. Kolb further exemplifies these compounds using a broad class of examples of polymers, non-polymeric compounds, and other substance types. Kolb makes no statement that the compounds within the list are limited to polymers only. Therefore, one reading the description must conclude that Kolb describes the specific compounds to be included within the list of suitable binding agents. Some of the compounds are specifically described as polymers. For example, biological cationic polymers, chitosan, SILGARD®, and polyacrylamides are polymers that are disclosed as binding agents [column 6, lines 22-25]. Some of the listed compounds may or may not be polymers. For example, quaternary ammonium, debonder, and softener are disclosed [column 6, lines 23-27] and are generic terms that could refer to either a polymer or a non-polymeric compound. Other compounds are not polymers. For example, liposome, diallyldimethyl ammonium chloride (DADMAC), and octadecyldimethoxylsilylpropylammonium chloride are not polymers.

Kolb does not disclose or suggest that polymers of diallyldimethyl ammonium chloride, nor polyDADMAC, are to be considered. Therefore, I conclude that Kolb does not disclose polyDADMAC as a binding agent component of a pant-like absorbent swimwear garment.

On further review of Kolb, I did not find any reference to the generic class of compounds, diallyldialkyl ammonium salts, recited in claims of the above-captioned application. In Kolb there is no mention of diallyldialkyl ammonium salts as either monomers or polymers. Thus, I conclude that Kolb does not disclose polymers of diallyldialkyl ammonium salts as suitable binders for use in the invention.

Verification

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.



November 5, 2009

Dr. James F. Kirk

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
James F. Kirk	VP, R&D

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Massachusetts Institute of Technology, Cambridge, MA	B.S.	1983	Mech. Engineering
Massachusetts Institute of Technology, Cambridge, MA	M.S.	1986	Materials Sci. & Eng.
Boston University, Boston, MA	MBA	1989	Management
University of Florida	Ph.D.	1997	Materials Sci. & Eng.

A. Positions and Honors. List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.

2008 **VP, R&D, Nanotherapeutics, Inc., duties include formulation research and development, manufacturing, SOPs, and project management.**

2004–2008 **Director, Manufacturing, Nanotherapeutics, Inc.,**

2000–2003 **Manager, Research, Regeneration Technologies, Inc., Alachua, FL, with responsibility for** 10 reports and budget of ca. $1.5M. RTI is one of the largest orthopedic tissue banks. Duties included oversight of outside studies; scientific direction/oversight of five programs (ranging from new processing technology to new product identification); and technical advisory on new marketing initiatives.

1997–2000 Sr. Process Engineer, Vistakon (Johnson & Johnson Vision Care), Jacksonville, FL, Process development team for new extended-wear contact lens.

1989-1992 Research Scientist I in product R&D group, Genzyme Corp., Boston, MA, Worked on development of biodegradable implants used as surgical aids. Responsible for scale-up and transfer of film based product to manufacturing.

B. Selected peer-reviewed publications (in chronological order).

Patents (in chronological order).

1. Compositions of and Methods for Preparing a Composition for Bone Repair, and Uses Thereof, J. **Talton and J. Kirk, Assignee: Nanotherapeutics, Inc., Patent Pending (2004).**
2. Molds for making ophthalmic devices, JD Ford, JF Kirk, FF Molock, Assignee: Johnson & Johnson **Vision Care, Inc., US Patent #6,551,531 (2003).**
3. Method and composition for preventing surgical adhesions and tissue damage employing fluorinated polymers, EP Goldberg, JF Kirk, LS Peck, Assignee: University of Florida, US Patent #6,090,997 (2000).
4. **Portable battery-powered safety lock, JP West, J Kirk, JF Kirk, US Patent #5,704,151 (1998).**
5. Prosthesis for promotion of nerve regeneration, IV Yannas, JF Kirk, etal, Assignee: MIT, US Patent #4,955,893 (1990).
6. **Method for the preparation of collagen-glycosaminoglycan composite materials, IV Yannas, JF Kirk, Assignee: MIT, US Patent #4,448,718 (1984).**